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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Holton, Zhang, and Clark

Possible Examiner: B. Trinh

Washington, D.C.

Filed: 20 April 1998

May 15, 2000

For: PROCESS FOR SELECTIVE

DERIVATIZATION OF

DIrector John Kittle

PROTEST UNDER 37 CFR 1.291(a)

Honorable Director of the U.S. PTO Washington, D.C. 20231

Sir:

Regarding the above listed application, believed to be pending as Application 09/063,477 and/or a continuing application thereof, please consider the additional material information as follows:

## MATERIAL PRIOR ART PATENT

Attention is invited to U.S. Pat No. 5,874,595 to Damen et al (copy attached). Damen '595 has a filing date of May 21, 1997, before the filing date of the provisional applications (60/056,000 filed August 18, 1997 and 60/081,265 filed April 9, 1998) on which the above mentioned application may be based, and is therefore "prior

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art" under at least 35 U.S.C. 102(e) and possibly 102(e) and/or (f).

## Remarks

Damen '595 relates to a method for the preparation of baccatin III and derivatives thereof from 10-deacetylbaccatin III.

It is observed that deactylbaccatin is abbreviated in U.S. Application 09/063,477 as DAB. Damen '595 discloses the preparation of baccatin III by subjecting 10-deacetylbaccatin III to an acylation reaction, which is catalyzed by a Lewis acid (e.g., see claim 1).

The acylating agent to be used can be anhydride, e.g. see claims 1 and 17, while the Lewis acid to be used can be a compound  $ML_x$  (e.g., see column 4, line 36), wherein M represents an element from the group of lanthanide elements (e.g., see claim 2), and L represents a counter ion, such as a triflate (e.g., see claims 3 and 4).

As indicated at column 3, line 66 - column 4, line 2, of Damen '595, the process results in the introduction of an acyl group at the C-10-hydroxyl position of 10-deacetylbacctin III (a taxane). At column 4, lines 30 - 34, the above process is applicable to the acylation with anhydrides or mixed anhydrides of any carboxylic acid

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or acyl halides to prepare any C-10-O-acyl derivative of 10-deacetylbaccatin III.

Damen '595 should therefore be considered to be highly pertinent prior art against application 09/063,477, especially as claimed in claim 1 and its depending claims 2-19 of the corresponding published EPA 0956284 based on WO 99/09021, which claims priority from 09/063,477.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.

Rv

Sheridan Neimark

Registration No. 20,520

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## CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing PROTEST was mailed by depositing with the U.S. Postal Service, with sufficient postage as first class mail, addressed to Edward J. Hejlek, Esq., Senniger, Powers, Leavitt & Roede, 16<sup>th</sup> Floor One Metropolitan Square St. Louis, MO 63102, this 15 May 2000.

Sheridan Weimark